



# **Medical Chemical and Biological Defense Research**

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# Medical Chemical/Biological Defense

## Rationale for Investment

- *...the threat or use of NBC weapons is “a likely condition of future warfare.” Quadrennial Defense Review (May 1997)*
- **Direct payoff of chemical/biological defense R&D:** Reduction, even elimination, of casualties which would otherwise follow a CW/BW attack.
- **Indirect payoffs:** Effective products against CW/BW deter employment and proliferation of CW/BW capabilities.
- **Efforts address Joint Service/CINC requirements**



# Medical Chemical and Biological Defense Research Program Mission

- **Provide medical solutions for military requirements to protect and sustain the force in a Chemical and/or Biological Warfare environment**





# MCBDRP Vision

- **To Preserve Total Warfighter Effectiveness on a CW/BW Battlefield**
  - Prevent casualties
  - Provide effective treatment of casualties for rapid return to duty
  - Provide rapid, far-forward diagnosis of CW/BW disease







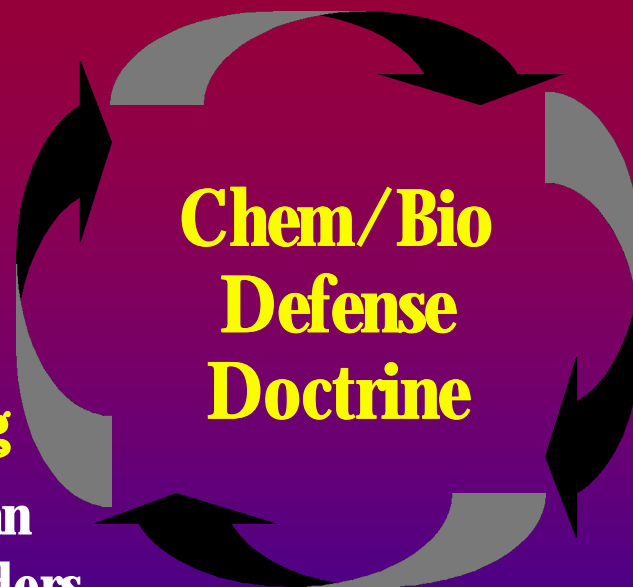
# Protecting Warfighters Through Integration and Teamwork

## Intelligence

- » Agent
- » Delivery System
- » Organization
- » Time

## Education & Training

- » Military and Civilian Health Care Providers
- » Electronic Communication
- » Distance Learning



## Medical Countermeasures

- » Vaccines & Prophylaxes
- » Diagnostics
- » Therapeutics

## Physical Countermeasures

- » Detection
- » Physical Protection
- » Decontamination



# Product Development Overview





# The “Tech Base” Products

- **Basic Research Discoveries (Scientific Knowledge)**
- **Model Development for Agents of DoD Interest**
- **Vaccine/pretreatment Candidates**
- **Therapeutic Candidates**
- **Diagnostic Tests and Reagents**
- **Information**
- **Education**
- **Expertise & Consultation**
- **Technology Watch**

## **Tech Base**

**Our Readiness Posture For Meeting Future Threats And Avoiding  
Technological Surprise**





# Medical Biological Defense

## ➤ **Technical Approach:**

- Identify mechanisms involved in disease process.
- Develop and evaluate products (vaccines or drugs) to prevent or counter effects of biological toxins, bacteria, and viruses.
- Develop methods to measure effectiveness of medical countermeasures in animal models which are predictive of human response.
- Develop diagnostic systems and reagents.



# Medical Biological Defense Organizational Taxonomy

## MEDICAL BIOLOGICAL DEFENSE

### Medical Countermeasures (MC) against BW Agents

#### DTO Efforts

- CB.24 MC for Encephalitis Viruses
- CB.25 Multiagent Vaccines for Biological Threat Agents
- CB.26 Common Diagnostic Systems
- CB.31 MC for Brucellae
- CB.32 Needleless Delivery Methods for Recombinant Protein Vaccines
- CB.33 Recombinant Protective Antigen (rPA) Vaccine Candidate
- CB.34 Recombinant Plague Vaccine Candidate

#### TASK AREAS

##### Vaccines

##### Therapeutics

##### Diagnostics



# Medical Biological Defense Transitions

- **FY99/00**
  - Multivalent (A,B,C,E,F) Recombinant Botulinum Vaccine - MS I
  - Plague (F1-V) Antigen Vaccine - MS 0
  - Recombinant VEE Vaccine - MS 0
  
- **FY01**
  - Next Generation Anthrax Vaccine - MS I
  - Plague (F1-V) Antigen Vaccine - MS I
  - Common Diagnostics - MS 0
  - Multiagent Vaccine - MS 0
  - Brucella Vaccine - MS 0
  - Marburg (Filovirus) Vaccine - MS 0



# Medical Biological Defense Products in Development (Projected Fielding)

- **Q-Fever Vaccine – 2004 ?**
- **Smallpox Vaccine (Cell Culture Derived) - 2005**
- **Recombinant Plague Vaccine - 2006**
- **Venezuelan Equine Encephalitis Vaccine - 2008**
- **Tularemia Vaccine - 2008**
- **Recombinant Botulinum Vaccine - 2009**
- **Brucella Vaccine - 2010**



# Emerging Medical BD Products

- **VEE/EEE/WEE Combined Vaccine**
- **Staphylococcal Enterotoxins Vaccine**
- **Ricin Vaccine**
- **Common Diagnostic System for BD Threats and ID Diseases**
- **Next Generation Anthrax Vaccine**



# Medical Biological Defense Investment in the Future

- **Countermeasures for Genetically Engineered Microbes**
  - Genomic sequencing of BW threat agents to identify and understand virulence factors, toxins and drug resistance genes
- **Immunomodulators and Therapies**
  - Alternatives to agent-specific vaccines or therapies
- **Multiagent Vaccines**
  - Alternative to one vaccine for one BW threat agent





# Strategic Challenges Medical Chemical and Biological Defense RDT&E

- **Acquisition Model**
- **FDA Regulations**
- **Multiplicity of Threats**



# Strategic Challenges

## ➤ Acquisition Model - Linear

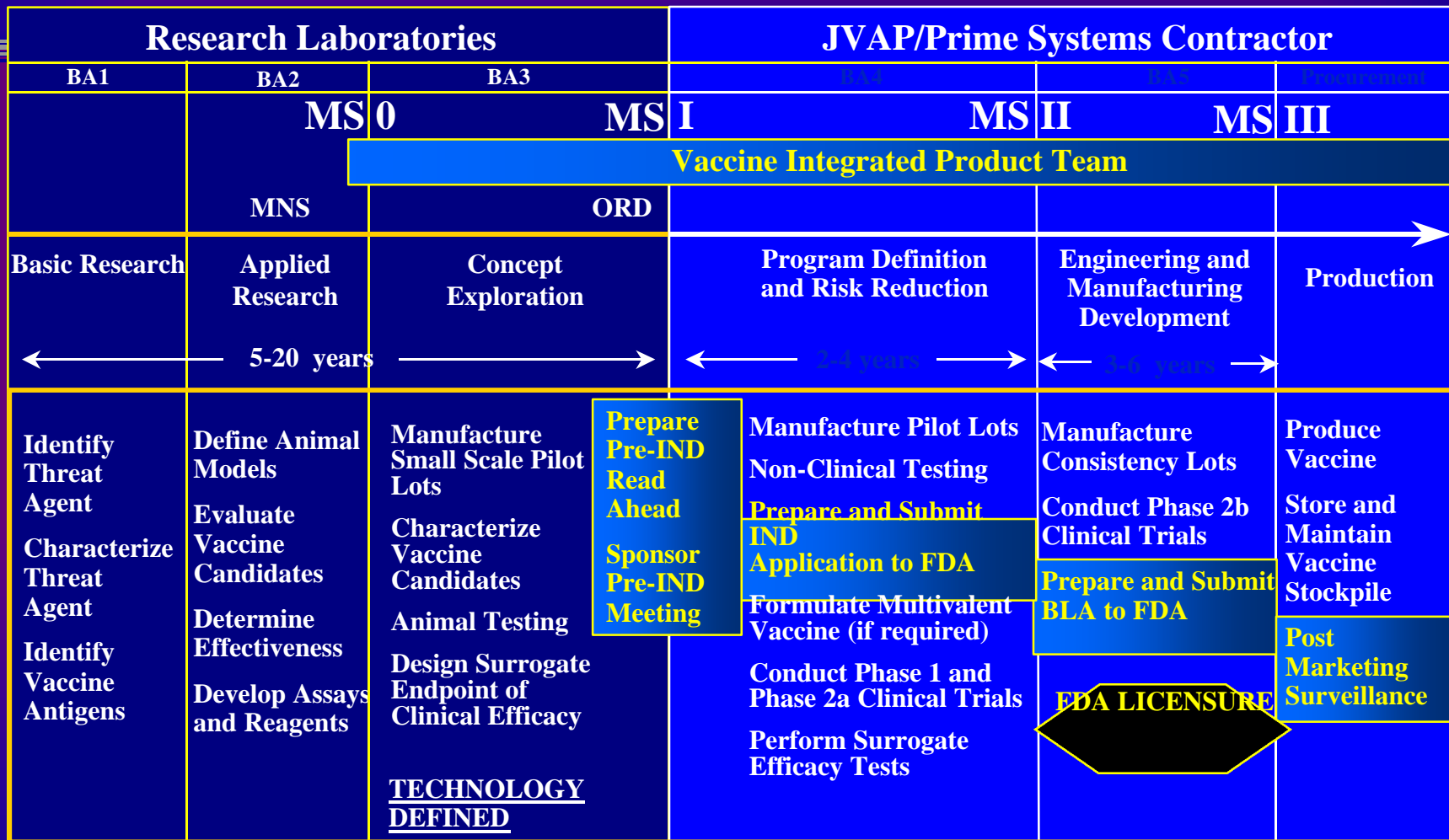
- Old DoD 5000
- New DoD 5000
- Technology Readiness Levels
- Risk Reduction

## ➤ Biologicals/Pharmaceuticals – Recursive

- Iterative testing of numerous candidates
- Kill products early
- Finite lifetime

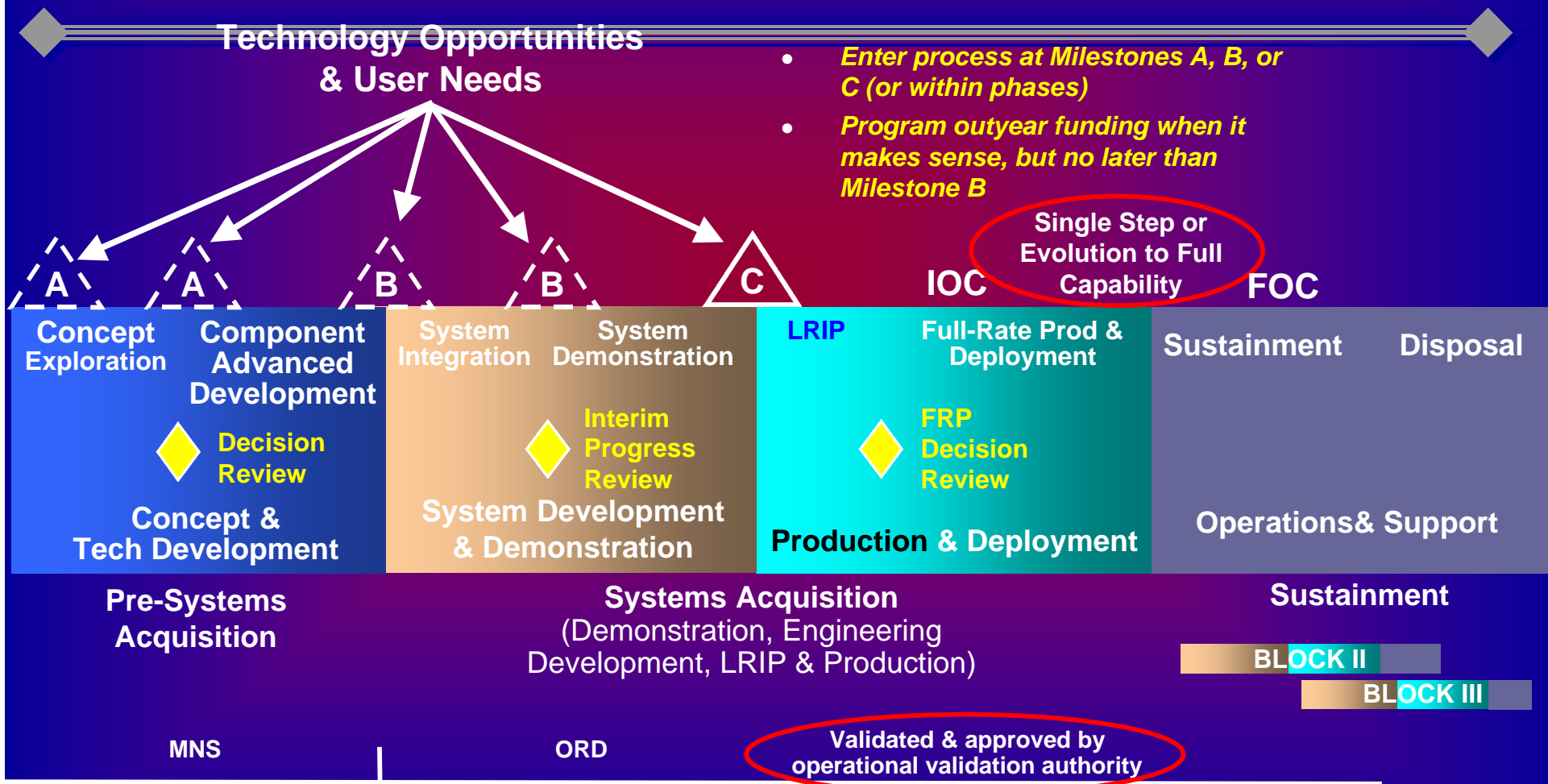


# Integration of DoD Milestones and FDA Licensure Process





# Defense Acquisition Management Framework





# Strategic Challenges

## ➤ **FDA Regulatory Requirements**

- **Products must be safe**
  - ↳ Demonstrate in animals
  - ↳ Demonstrate in humans
- **Products must be effective**
  - ↳ Demonstrate in animals
  - ↳ Demonstrate in human clinical studies and field trials

## ➤ **Medical Chem/Bio Products – we can:**

- Demonstrate safety in animals and humans
- Demonstrate efficacy in animals
- Estimate efficacy in humans



# Strategic Challenges

## ➤ **Proposed new FDA Rule**

- **Allows consideration of animal efficacy studies in support of licensure request**
- **Additional requirements**
  - **Understand mechanisms of action of the disease-causing agent**
  - **Understand basis of action of the vaccine or drug**
  - **Demonstrate efficacy in two relevant animal models**
  - **Identify surrogate markers of efficacy**





# Strategic Challenges

- **Multiplicity of Threats**
  - **Chemical Warfare Agents**
    - ↳ Nerve agents
    - ↳ Mustards
    - ↳ Blood/Choking agents
  - **Biological Warfare Agents**
    - ↳ Viruses
    - ↳ Bacteria
    - ↳ Toxins
  - **Emerging Threats**



# Summary

- **Medical chemical and biological defense research presents unique challenges**
  - Chemical threat agents
  - Biological threat agents
  - Medical regulatory compliance and DoD acquisition
- **We need cutting edge technologies to develop medical countermeasures for the warfighter**
  - Biotechnology
  - Informatics
  - Genomics and Proteomics
- **Partnerships with the science community & industry are essential**
  - CRADAs
  - Contracts